K063499
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510(k) SUMMARY

1. SUBMITTER:

Scandius Biomedical, Inc.
11A Beaver Brook Road
Littleton, MA 01460

DEC 19 2006

Contact: Ralph Zimmerman, Quality Assurance Manager
Date Prepared: November 17, 2006

2. DEVICE:

Trade Name: Scandius TriTis™ Tibial ACL Reconstruction System
Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue
The Product Code: MBI

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for modifications to the Scandius TriTis Tibial ACL Reconstruction System was the previously cleared Scandius TriTis Tibial ACL Reconstruction System.

4. DEVICE DESCRIPTION:

The TriTis Tibial ACL Reconstruction System consists of a three piece implant designed to provide soft tissue fixation for tibial anterior cruciate ligament (ACL) reconstruction. The graft cleat secures the soft tissue graft in the tunnel. The washer and fixation screw secure the ends of the graft and cleat to the bone.

The System includes instrumentation to prepare the bone tunnel and place the device as well as a sterilization tray.

The modifications made to the device that are the subject of this submission are:

Add a new, 12 mm diameter graft cleat implant size, and a new, 12 mm Dilator instrument. All other device features and instruments remain unchanged.

5. INTENDED USE:

The TriTis Tibial Fixation System is intended for use in the fixation of ligament and tendon grafts during anterior cruciate ligament (ACL) reconstruction of the knee.

6. COMPARISON OF CHARACTERISTICS:

- The devices have the same intended and indication for use, and have similar technical characteristics and principles of operation
- The devices use the same implant materials
- Bench testing demonstrates that any minor technological differences do not raise any new questions of safety and effectiveness.

7. PERFORMANCE DATA:

The following performance data was generated in support of the substantial equivalence determination:

- Simulated use test to confirm that design integrity is maintained
- System strength test to confirm that design integrity is maintained

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scandius Biomedical, Inc.
c/o Mr. Ralph Zimmerman
Quality Assurance Manager
11A Beaver Brook Road
Littleton, MA 01460

DEC 19 2006

Re: K063499
Trade/Device Name: Scandius TriTis™ Tibial ACL Reconstruction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, HWC
Dated: November 17, 2006
Received: November 20, 2006

Dear Mr. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063499

Device Name: Scandius TriTis™ Tibial ACL Reconstruction System

Indications for Use: The TriTis Tibial Fixation System is intended for use in the fixation of ligament and tendon grafts during anterior cruciate ligament (ACL) reconstruction of the knee.

Prescription Use __X__
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063499

(Optional Format 1-2-96)